DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

THROUGH: Vincent Tolino___/S/__11/7/06
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

FROM: Kathleen L. Walker __/S/_____10/27/06
Chief, Integrity, Committee and Conference Management Branch
Division of Ethics and Management Operations, OMO
Center for Devices and Radiological Health

SUBJECT: Conflict of Interest Waiver for Richard L. Page, M.D.

I am writing to request a waiver for Richard L. Page, M.D., a member of the Circulatory System Devices Panel of FDA's Medical Devices Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a). Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved" and where the individual has made a disclosure of the financial interests at issue. We have determined that you are the appointing official for purposes of section 208. Therefore, you have the authority to grant Dr. Page a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which the employee or his employer has a financial interest. Since Dr. Page is a special Government employee, this individual is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or his employer.

Dr. Page has been asked to participate in the Panel's discussion of issues related to stent thrombosis in coronary drug-eluting stents (DES). These stents contain drugs that potentially reduce the chance the arteries will become blocked again. The discussion will also include issues regarding the association between DES thrombosis and the [----------].
Thirty-three firms are currently identified as manufacturers of stent, drug or delivery components, and 18 firms produce devices that are alternative technologies to drug-eluting stents. These matters are coming before the Circulatory System Devices Panel for consideration and are particular matters of general applicability.

Dr. Page has advised the FDA that he has financial interests which could potentially be affected by his participation in this matter. He reported an unrelated consulting arrangement with [--- ----------], to provide advice concerning [---------- ----------]. Consultation fees received in [----------]. Although Dr. Page has not performed any work for [----------] within the past year, the contract has been [----------] with an estimated earning of less than [-----]. Relevant to this meeting, [--- ----------] is not a firm at issue; however, another subsidiary of [----------], [----------], is a stent manufacturer as well as a manufacturer of alternative technologies.

He also reported a consulting arrangement with [----------], the manufacturer of [----]. This arrangement, unrelated to the issues before the Panel, has been [----------] and involves his expert advice on [----------]. Total amount received thus far in [------ ------]; additional fees not to exceed [----]. He anticipates working for them until [-------] with an expected earning between [-----] and [------].

The functions of the committee, as stated in its Charter, are to review and evaluate available data concerning the safety and effectiveness of marketed and investigational devices and advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories; recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemption to certain devices from the application of portions of the Act; advise on the necessity to ban a device; and respond to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. As a member of the Circulatory System Devices Panel, Dr. Page potentially could become involved in matters that affect [----------] and [----------]. Under section 208, Dr. Page is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. §208(b)(3) to grant a waiver permitting this individual to participate in such matters, as you deem appropriate.

For the following reasons, I believe it would be appropriate for you to grant a waiver to Dr. Page allowing him to participate in matters identified below.

First, the issues to be addressed by the Panel are particular matters of general applicability, involving an entire class of products and granting no advantage to any individual manufacturer. Therefore, the Panel recommendations would not be expected to have a significant financial impact on any specific firm and the potential perception of bias on the part of the SGE should be mitigated.

Second, given the nature of Dr. Page's unrelated consulting arrangements with [--- ----------] and [--- ---------], it is unlikely that recommendations of the Panel will impact the viability of these firms or his ongoing relationships with them. Therefore, potential concern that Dr. Page's impartiality might be called into question during Panel deliberations should be diminished.

Third, the Panel's role is advisory in nature and the Agency officials making the decisions are not bound by the recommendations of the Panel. Therefore, the Agency will take into consideration the SGE's interests when making a final decision.

Lastly, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interest and affiliations they may have acquired as a result of their demonstrated abilities. Dr. Page is Professor and Head of the Division of Cardiology at the University of Washington School Of Medicine and is an attending physician at the University of Washington Medical Center, Harborview Medical Center and Puget Sound VA Medical Center. With his background in cardiac electrophysiological research, Dr. Page brings a perspective that will help the Panel to determine how to approach recent data concerning drug-eluting stents. Specifically, the recent post-market problems with implantable cardiodefibrillators pose the same sort of dilemmas as the post-market issues associated with drug-eluting stents. In both cases one is dealing with a very useful chronic implant that in rare cases can have adverse consequences and produce significant morbidity and mortality. As a result of his recent experience with the post-market defibrillator problems, Dr. Page should be able to thoughtfully address the post-market DES issue and help determine how to communicate issues related to those events to patients. This communication will be critical to the Panel discussion intended to help FDA frame its educational efforts.

Accordingly, I recommend that you grant Dr. Page a waiver allowing him to participate fully in all official matters before the Panel regarding issues related to stent thrombosis in coronary drug-eluting stents. I believe that such a waiver is appropriate because in this case, the need for the services of Dr. Page outweighs the potential for a conflict of interest created by the financial interest involved.

CONCURRENCE: __/S/_____ 11/7/06
Vincent Tolino Date
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

DECISION:

____X_____ Waiver granted based on my determination made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for conflict of interest created by the financial interest attributable to the individual.

_____ Waiver denied.

__/S/_____ 11/16/06
Randall Lutter, Ph.D. Date
Associate Commissioner for Policy and Planning